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10/524,821	02/18/2005	Degenhard Marx	26581U	1652
34375 7590 06/16/2010 NATH & ASSOCIATES PLLC 112 South West Street			EXAMINER	
			JEAN-LOUIS, SAMIRA JM	
Alexandria, VA 22314			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/524,821 MARX ET AL. Office Action Summary Examiner Art Unit SAMIRA JEAN-LOUIS 1627 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 26 February 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1, 3-14, and 18-31 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1,3-14 and 18-31 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

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## DETAILED ACTION

### Response to Arguments

This Office Action is in response to the amendment submitted on 02/26/10.

Claims 1, 3-14, and 18-31 are currently pending in the application, with claims 2 and 1517 having being cancelled. Accordingly, claims 1, 3-14, and 18-31 are being examined on the merits herein.

Receipt of the aforementioned amended claims, Information Disclosure Statement (IDS) and Declaration is acknowledged and has been entered.

Applicant's argument with respect to the 103 (a) rejections over Magee or Szelenyl in view of Schmidt has been fully considered. Applicant argues that Magee does not establish a prima facie case of obviousness since Magee recites a laundry list of potential active ingredients and does not suggest the combination of the two specific ingredients as required by the instant claims. Additionally, applicant argues that one of ordinary skill in the art would have no reason to modify Magee containing ciclesonide and azelastine to achieve a hypotonic composition. Such arguments are however not found persuasive as the Examiner reiterates the arguments in the Non-Final Office Action dated 09/30/09. The Examiner respectfully points out that the disclosure of Magee clearly renders obvious applicant's invention since Magee teach the use of PDE4 inhibitors in combination with active ingredients for the treatment of chronic rhinitis (see Magee, pg. 1, paragraph 0006). Examples of such active ingredients that

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can be used in combination with the PDE4 inhibitors include ciclesonide and antihistamine receptor antagonists such as azelastine (see Magee, pg. 34, paragraph 0218). Thus, regardless if Magee discloses several ingredients, one of ordinary skill in the art would have found it obvious to choose the aforementioned combination and have a reasonably expectation of success since Magee teaches the aforementioned ingredients in combination with PDE4 inhibitors for the treatment of rhinitis. Additionally, the Examiner reiterates the fact that the presence of the term "comprising" does not exclude addition of other active ingredients hence the reason why Magee renders such claims obvious.

As for Dr. Rolf Beume's declaration and applicant's arguments that the claim subject matter shows unexpected results, the Examiner maintains that the unexpected results do not commensurate in scope with the claims. While such declaration teaches that ciclesonide in combination azelastine leads to reduction in sneezes and rubbing, the claims as presently recited (i.e. containing the term "comprising") envisioned addition of other ingredients wherein a combination of ciclesonide and azelastine is also expected. Instead, the Examiner suggests that applicant amends the claim to either recite a "consisting-type of language" or recite that the "only two active ingredients" are ciclesonide and azelastine in order to overcome the prior art references.

As for Calatayud, it was provided to demonstrate that R and S epimers of ciclesonide can be made as a mixture for therapeutic agents. Importantly, Calatayud teaches that the mixture of R and S epimers possesses a high anti-inflammatory activity and high therapeutic index with minimal side effects. Consequently, one of ordinary skill

in the art at the time of the invention would have found it obvious to utilize the mixture of ciclesonide in the composition of Magee since Calatayud teaches that the mixture of ciclesonide possesses a high therapeutic index with minimal side effects.

Regarding applicant's argument over Szelenyl in view of Schmidt, the Examiner again reiterates the fact that Szelenyl was provided to demonstrate that the soft steroid, ciclesonide, is effective in treating allergic rhinitis without producing local or systemic effects. Consequently, the Examiner contends that one of ordinary skill in the art would have found it obvious to substitute the soft steroid ciclesonide of Schmidt for the soft steroid loteprednol of Szelenyl since Schmidt teaches that ciclesonide is effective in treating allergic rhinitis without the complication of local or systemic effects. As a result, the Examiner maintains that Szelenyl in view of Schmidt does indeed render obvious applicant's invention. Moreover, given that the combination of the two aforementioned ingredients results in an osmotic effect, the Examiner maintains that such osmotic pressure would necessarily come about as a result of the modification taught by Szelenyl and Schmidt.

Regarding the show of unexpected results, the Examiner again refers applicant to the aforementioned argument that while there is a show of unexpected result, the claims as presently recited do not commensurate in scope. Instead, the Examiner suggests that applicant's amend their claims to recite that the "sole" or that the "only two active ingredients" are ciclesonide and azelastine. However, until such amendment is made, the prior art references do indeed render obvious applicant's instant claims.

For the foregoing reasons, the rejections of record under 103 (a) remain proper and are maintained. However, in view of applicant's amendment, the following modified 103 (a) Final rejections are being made.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-14, 18, 20-23, 25-28, and 30-31 are rejected under 35 U.S.C. 103
(a) as being unpatentable over Magee et al. (U.S. 2002/0111495 A1, previously cited).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Magee et al. teach the use of selective PDE4 inhibitors for improved therapeutic treatment of a number of inflammatory, respiratory and allergic diseases including chronic rhinitis (i.e. allergic rhinitis; instant claim 18; see pg. 1, paragraph 0006 and pg. 81, paragraphs 0467-0472). Magee et al. further teach that the present compounds can be used together in combination with one or more therapeutic agents including antihistaminic H2 receptor antagonists such as azelastine (instant claims 1 and 18), the steroid ciclesonide and pharmaceutically carriers (instant claim 1; see pg. 34, paragraph 0218 and pg. 92, paragraph 0570-0571). The compositions of Magee et al. can be administered to humans (instant claim 20; see pg. 76, paragraph 0423). Magee et al. further teach that the route of administration can critically affect bioavailability, solubility of the active agents and rapid absorption (see pg. 100, paragraph 0677). By carriers, Magee et al. teach addition of acceptable diluents, adjuvants, vehicles viscosity modifiers and other agents known to the artisan for providing favorable properties to the final pharmaceutical composition including water as a solvent, salts such as sodium chloride for isotonic properties (i.e. osmotic pressure-controlling agent; instant claim 7), cellulose-based substances such as sodium carboxymethylcellulose (i.e. water soluble polymer; instant claims 8-9 and 12), polyethylene glycol as a wetting agent, polyethylene polyoxypropylene block polymer as a surfactant (instant claim 13), emollients, humectants such as glycerin (instant claim 13), surfactants and sugars such

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as glucose (instant claim 7; see pg. 100-102, paragraphs 0677, 0688 and 0697-0698). Magee et al. further teach that the composition for intranasal application (i.e. nasal mucosa, instant claim 14; see pg. 104, paragraph 0708). Magee et al. also teach that the pharmaceutical compositions comprising any of the aforementioned compounds can comprise any of the aforementioned compound salt thereof derived from various organic and inorganic acids and that it is within the scope of the skilled artisan and well known in the art to derive various pharmaceutical salts thus rendering obvious azelastine hydrochloride (instant claims 23, 26, 28, and 31: see pg. 99, paragraphs 0671-0672).

Magee et al. do not specifically teach a composition with a particular osmotic pressure or a composition containing microcrystalline cellulose as solid particles in an aqueous medium.

However, Magee et al. do teach the addition of water-low soluble substances such as cellulose derivatives which encompasses all substances containing cellulose including microcrystalline cellulose which are solid particles before addition to the pharmaceutical composition. Moreover, Magee et al. teach the use of viscosity modifiers and given that microcrystalline cellulose is a well-known viscosity modifier, one of ordinary skill would readily add such compound as solid particles as to obtain the desired product with the desired osmotic pressure. Additionally, Magee et al. teach the addition of osmotic pressure controlling agents including glucose and sodium chloride.

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Consequently, the Examiner maintains that these agents would necessarily affect the osmotic pressure of the composition due to their tonicity properties. Thus, to acquire the desired osmotic pressure for enhancing the bioavailability of the active ingredients as suggested by Magee et al., one of ordinary skill would have been motivated to vary the concentration of the osmotic pressure controlling agents in a particular form in the composition of Magee.

Moreover, applicant is reminded that a prior art reference may "render obvious" without disclosing a feature of the claimed invention, as long as that missing characteristic is necessarily present, or inherent, in the anticipating reference. Please see Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Other precedents of the court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. Please see, e.g., In re Cruciferous Sprout Litig, 301 F.3d 1343, 1351 (Fed. Circ. 2002); MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999) (Where the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results". In the instant case, the unappreciated osmotic pressure of Magee's composition does not require recognition by Magee et al.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Magee et al. to treat allergic rhinitis while varying the concentration of the osmotic pressure controlling agents since Magee et al. teach that addition of osmotic pressure agents can lead to enhancement of the

bioavailability of the active ingredients in the composition. Given that Magee et al. teach a method of treating allergic rhinitis with PDE4 inhibitors, azelastine and ciclesonide with additional excipients, one of ordinary skill would have been motivated to utilize the method of Magee et al. and vary the concentration of water soluble agents and osmotic pressure controlling agents with the reasonable expectation of providing a composition that is efficacious in treating allergic rhinitis and a composition that is readily absorbed.

Claims 19, 24, and 29 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Magee et al. (U.S. 2002/0111495 A1, previously cited) as applied to claims 1, 3-14, 18, 20-23, 25-28, and 30-31 and in further view of Calatayud et al. (U.S. 5,482,934, previously cited).

The Magee reference is as discussed above and incorporated by reference herein. However, Magee does not specifically teach the mixture of the "R" and "S" epimers in a mixing ratio into the composition.

Calatayud et al. teach compounds of the general formula

with X1 an X2 corresponding to H and R1 is a phenyl group and R2 represents radicals such as C=OCH(CH3)CH3 in the form of an R epimer, S epimer or mixture of the R and S epimers (i.e. ciclesonide) as drugs and/or therapeutic agents (see abstract and col. 3, lines 1-61). Calatayud et al. further teach that these compounds possess intense pharmacological activity with no or minimal systemic effects (see col. 2 lines 21-23, col. 15, lines 10-11 and col. 16, lines 27-30). Calatayud et al. also teach synthesis of the mixture of ciclesonide with both the R and S epimers in a ratio of 45/55 of R/S (see col. 11, lines 21-61). Importantly, Calatayud et al. teaches that the mixture of R and S epimers of ciclesonide possess high anti-inflammatory activity, high glucocorticoid activity and high therapeutic index (see col. 17-18, table 2-3 compounds 7-9).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute the R-epimer or the mixture of epimers of ciclesonide into the composition of Magee et al. to treat allergic rhinitis while varying the concentration of the osmotic pressure controlling agents since Calatayud et al. teach that R-epimer can be isolated and given that the mixture of epimers possesses intense glucocorticoid and therapeutic activities with minimal systemic effects. Given that Magee et al. teach a method of treating allergic rhinitis with PDE4 inhibitors, azelastine and ciclesonide with additional excipients, and Calatayud et al. teach the isolation of the R-epimer or the use of mixtures of epimers of ciclesonide with high glucocorticoid activity and minimal systemic effects, one of ordinary skill would have been motivated to substitute either the R-epimer or the mixture of epimers of ciclesonide into the composition of Magee et al.

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with the reasonable expectation of providing a composition that is efficacious in treating alleroic rhinitis and a composition that is readily absorbed with no systemic effects.

Claims 1, 3-14, 18, 20-23, 25-28, and 30-31 are rejected under 35 U.S.C. 103
(a) as being unpatentable over Szelenyl et al. (WO 01/22955, previously cited) in view of Schmidt et al. (J. Clin. Pharmacol. 1999, Vol. 39, pgs. 1062-1069, previously cited).

WO 01/22955 is the PCT counterpart to U.S. 7,022,687 B1. WO 01/22955 A1 is prior art under U.S.C. 102 (b) as a result of its April 05, 2001 publication date. U.S. 7,022,687 B1 is prior art under U.S.C. 102 (e). Because WO 01/22955 and U.S. 7,022,687 B1 appear to have identical disclosures, the U.S. patent is being used as a translation of WO 01/22955 PCT. While any reference hereinafter to column and line numbers will be based upon the U.S. patent disclosure, such reference should be interpreted as referring to the corresponding disclosure of the aforementioned PCT counterpart.

Szelenyl et al. teach the combination of a soft steroid such as loteprednol and at least one antihistamine, such as azelastine and/or levocabastine for the local treatment of allergies and airway disorders including allergic rhinitis (instant claims 1 and 18; see abstract and col. 6, claims 1-2, 4-5, 8). The administration can be intranasal (instant claim 14; see col. 1, line 66, and col. 2, line 53) and can further include solvents such as water, preservatives, water soluble polymer stabilizers such as sodium carboxymethyl-cellulose or mixtures of microcrystalline cellulose and sodium carboxymethylcellulose

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known as Avicel RC (instant claims 8-9, 11-12, and 21), isotonicizing agents such as sodium chloride or glucose (i.e. osmotic pressure controlling agents; instant claim 7), and suitable wetting agents (instant claim 13; col. 4, lines 5-14, 29-33, and 45-67). Additionally, Szelenyl et al. teach that azelastine hydrochloride can be used for its water solubility and used in solutions (see col. 3, lines 65-67; instant claims 23, 26, 28 and 31).

Szelenyl et al. do not particularly teach a composition containing ciclesonide. Similarly, Szelenyl et al. do not teach a composition with a specific osmotic pressure value or a composition containing microcrystalline cellulose as solid particles in an agueous medium.

While Szelenyl et al. do not teach particular osmotic pressures, he does teach the addition of water soluble substances along with isotonicizing agents which are solid particles in nature in the composition wherein their addition would necessarily affect the osmotic pressure. Thus, it would have been well within the purview of the skilled artisan to experiment with varying concentrations of the aforementioned compounds and various forms of the aforementioned products during routine experimentation in order to obtain the desired product with the desired osmotic pressure.

Schmidt et al. teach the use of the soft steroid, ciclesonide, as an effective steroid in the treatment of allergic rhinitis without producing local or systemic effects (see abstract). Schmidt et al. further teaches that ciclesonide has an "R" epimer with a

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higher binding affinity than the "S" epimer to the glucocorticoid receptor (see pg. 1063, left col. paragraph 1). This compound can be administered intranasally (see pg. 1063, right col. paragraph 1), was found to be highly effective in the treatment of allergic rhinitis, and led to a rapid alleviation of symptoms without producing systemic side effects (see pg. 1069, left col., last paragraph).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute the ciclesonide of Schmidt et al. for the loteprednol of Szelenyl et al. to treat allergic rhinitis since Schmidt et al. teach that ciclesonide possesses low systemic effects. Moreover, as a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) MPEP 2144.06.

Given that Szelenyl et al. teach a composition containing a soft steroid and antihistamines for treating allergic rhinitis with additional excipients, and Schmidt et al. teach the soft steroid ciclesonide is effective in treating allergic rhinitis without producing local or systemic effects, one of ordinary skill would have been motivated to substitute the ciclesonide of Schmidt et al. for the loteorednol of Szelenyl et al. with the reasonable

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expectation of providing a composition that is efficacious in treating allergic rhinitis and a composition with minimal side effects.

Claims 19, 24, and 29 are rejected under 35 U.S.C. 103 (a) as being unpatentable over unpatentable over Szelenyl et al. (WO 01/22955, previously cited) in view of Schmidt et al. (J. Clin. Pharmacol. 1999, Vol. 39, pgs. 1062-1069, previously cited) as applied to claims 1, 3-14, 18, 20-23, 25-28, and 30-31 and in further view of Calatayud et al. (U.S. 5.482,934, previously cited).

The Szelenyl et al. reference is as discussed above and incorporated by reference herein. However, Szelenyl et al. do not particularly teach the mixture of the "R" and "S" epimers in a mixing ratio into the composition.

Calatayud et al. teach compounds of the general formula

with X1 an X2 corresponding to H and R1 is a phenyl group and R2 represents radicals such as C=OCH(CH3)CH3 in the form of an R epimer, S epimer or mixture of the R and S epimers (i.e. ciclesonide) as drugs and/or therapeutic agents (see abstract and col. 3, lines 1-61). Calatayud et al. further teach that these compounds possess intense pharmacological activity with no or minimal systemic effects (see col. 2 lines 21-23, col.

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15, lines 10-11 and col. 16, lines 27-30). Calatayud et al. also teach synthesis of the mixture of ciclesonide with both the R and S epimers in a ratio of 45/55 of R/S (see col. 11, lines 21-61). Importantly, Calatayud et al. teach that the mixture of R and S epimers of ciclesonide possess high anti-inflammatory activity, high glucocorticoid activity and high therapeutic index (see col. 17-18, table 2-3 compounds 7-9).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute the R-epimer or mixture of epimers of ciclesonide into the composition of Szelenyl et al. to treat allergic rhinitis since Calatayud et al. teach that the R-epimer can be made and that the mixture of epimers possesses intense glucocorticoid activity and high therapeutic index with minimal systemic effects. Given that Szelenyl et al. teach a composition of treating allergic rhinitis with azelastine or levocabastine and a soft steroid along with additional excipients, and Schmidt et al. teach the use of ciclesonide for treating allergic rhinitis with low systemic effects, and Calatayud et al. teach the synthesis of the "R" epimer and that mixtures of epimers of ciclesonide with high glucocorticoid activity and minimal systemic effects, one of ordinary skill would have been motivated to substitute either the "R" epimer or the mixture of epimers of ciclesonide for the "R" epimer into the composition of Szelenyl et al. with the reasonable expectation of providing a composition that is efficacious in treating allergic rhinitis and a composition that possesses no systemic effects.

#### Conclusion

No claims are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-

273-8300.

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/S. J. L./

Examiner, Art Unit 1627

06/13/2010

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627